

**Holmes**

1300 Centennial Drive  
Thief River Falls, Minnesota 56701

5315 '99 NOV 23 AIO 104

NOV.17,1999

DEAR SIR:

I AM ENCLOSING INFORMATION WHICH I HOPE WILL HELP YOUR CAUSE...

WILL YOU SEND YOUR FINDINGS TO BETTER HOMES AND GARDENS ALSO  
- GOOD HOUSEKEEPING...

I HAVE BEEN BOTHERED FOR 20 YEARS AND IT IS WORSE SENCE I AM GETTING  
OLDER. . . I ALWAYS GOT SICK AND FUNERALS AND WEDDINGS AND THINKING IT COULD  
BE THE FOOD. . . I QUIT EATING BUT STILL GOT SICK SO I **QUIT** GOING...

NOW I REALIZE THE EFFECTS "**FRAGRANCES**" HAVE ON ME AND I NOW HAVE  
A HOUSE SCENT FREE AND ALSO LOOK FOR AND BUY **SCENT FREE COSMETICE...**

I HAVE HAD HEART **FIBRILATIONS** AND NOW I AM ON **LANOXIN...** I HAVE HAD SO  
MANY RASHES.. . SHORTNESS **OF** BREATH AND GREYOUTS...

ANOTHER PERSON THAT GETS **SICK** THAT I KNOW IS: PEGGY PIATT  
327 N. KENDALL  
THIEF RIVER FALLS,MN. **56701**

PEGGY GETS SEIZURES FROM PERFUMES...

THANK YOU FOR ALL THE WORK YOU ARE DOING AND I AM IN HOPES THIS INFORMATION  
COMES OUT MORE AND PEOPLE BECOME MORE AWARE...

THIS IS MORE OF A PROBLEM TO ME THAN CIGARETTE SMOKE. . .

WITH RESPECT,

VAL HOLMES

99P-1340

C536

Dockets Management Branch  
**The Food** and Drug Administration  
Department of Health & Human Services, Rm. 1-23  
12420 **Parklawn** Dr.  
Rockville, MD 20857

Date: Nov 17, 1999

Re: **99P-1340/CP 1** — Petition to Have *Eternity eau de parfum* declared "**Misbranded**" <sup>5314</sup> '99 NOV 23 10:07

Dear Sir or 'Madam:

In May 1999, the Environmental Health Network (**EHN**) submitted the above petition to have Calvin Klein's *Eternity* eau de parfum declared "misbranded." I am writing because I fully support this petition and request that the **FDA** give it careful attention with regard to your regulations **21CFR** Sec. **740.1**, **21CFR** Sec. 740.2, and **21CFR** Sec. 740.10. Regulation **21CFR** Sec. 740.10 states:

Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately **substantiated for** safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

'Warning — The safety of this product has not been determined.'

As the petition shows, *Eternity* contains toxic ingredients and ingredients whose safety have not been substantiated. There is no warning label on its packaging.

We **all have** a right to know the status of safety testing of the ingredients in products *such as Eternity* so that we can protect ourselves and our families from toxic chemicals that may cause health problems. Most people are not aware that most fragrance materials have only limited safety testing. They wrongfully assume these products are safe to use in any setting and are surprised when people complain.

Like tobacco smoke, the harmful chemicals currently used in these products may affect the health of many people, including: people with asthma, chemical sensitivities, chronic fatigue, and other environmental illnesses. **Children** are particularly vulnerable to toxic **chemicals found in** products purchased and used by their parents, caregivers and teachers. **When I** am exposed to fragrance products I can experience any of the following symptoms based upon the chemical fragrance product I encounter:

- |  |   |  |   |
|--|---|--|---|
| <input type="checkbox"/> anaphylaxis/shock               | <input type="checkbox"/> double vision                      | <input type="checkbox"/> incoherence                 | <input type="checkbox"/> nausea                           |
| <input type="checkbox"/> anxiety, restlessness           | <input type="checkbox"/> ear pain                           | <input type="checkbox"/> incontinence                | <input type="checkbox"/> nose bleeds                      |
| <input type="checkbox"/> asthma                          | <input type="checkbox"/> eczema                             | <input type="checkbox"/> irritability                | <input checked="" type="checkbox"/> rashes                |
| <input checked="" type="checkbox"/> breathing difficulty | <input checked="" type="checkbox"/> eyes, watery or dry     | <input type="checkbox"/> joint aches                 | <input type="checkbox"/> seizures                         |
| <input type="checkbox"/> bronchitis                      | <input checked="" type="checkbox"/> fatigue                 | <input checked="" type="checkbox"/> laryngiti        | <input type="checkbox"/> short-term mem. loss             |
| <input type="checkbox"/> can't concentrate               | <input checked="" type="checkbox"/> flushing                | <input type="checkbox"/> lethargy                    | <input type="checkbox"/> sinusitis                        |
| <input checked="" type="checkbox"/> coughing             | <input checked="" type="checkbox"/> headaches               | <input type="checkbox"/> lymph nodes swell           | <input type="checkbox"/> sneezing                         |
| <input type="checkbox"/> "depression                     | <input checked="" type="checkbox"/> heart beat irregularity | <input type="checkbox"/> moodswings                  | <input type="checkbox"/> sores, skin/mouth                |
| <input type="checkbox"/> disorientation                  | <input type="checkbox"/> hives                              | <input type="checkbox"/> muscle pain/weakness        | <input checked="" type="checkbox"/> swallowing difficulty |
| <input type="checkbox"/> &-dizziness                     | <input type="checkbox"/> hypertension                       | <input checked="" type="checkbox"/> nasal congestion | <input type="checkbox"/> tinnitus                         |
| <input type="checkbox"/> other: _____                    |   |  |   |

Please act on behalf of the millions of people who have suffered physical illness and injury resulting from fragrance exposure at work, at school and in social settings. These toxic chemicals act as powerful barriers to people disabled by asthma and chemical sensitivities. Toxic chemicals in fragrances have already ruined countless lives. Thank you.

Sincerely,

VELMA L. HOLMES

your name

1300 CENTENNIAL DR - THIEF RIVER FALLS, MN 56201

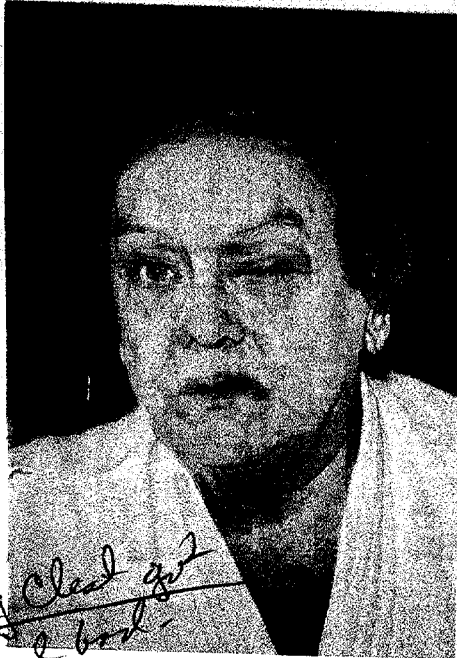
address; city/st/zip

Newsletters and everyone who feels people have a right to know, please copy, share, tell your friends and WRITE the FDA. . . today!

SOME OF THE REACTIONS I GET FROM PERFUME...LOTIONS...SOAPS...ECT.

I ALSO GET REACTIONS TO TREES...SPRAYS USED BY FARMERS...FOODS...SUCH AS CORN, SHELL FISH...FAKE SEASONINGS SUCH AS THEY PUT IN BRATS, BACON, SAUSAGE ECT.....  
I DO NOT LIKE TO GO TO FUNERALS, WEDDINGS, OR DRESSUP GATHERINGS AS PEOPLE USE TOO MUCH HAIR SPRAYS, PERFUMES AND I HAVE TO GO HOME WITH SWOLLEN THROAT...FACE OR I END UP IN THE EMERGENCY ROOM...

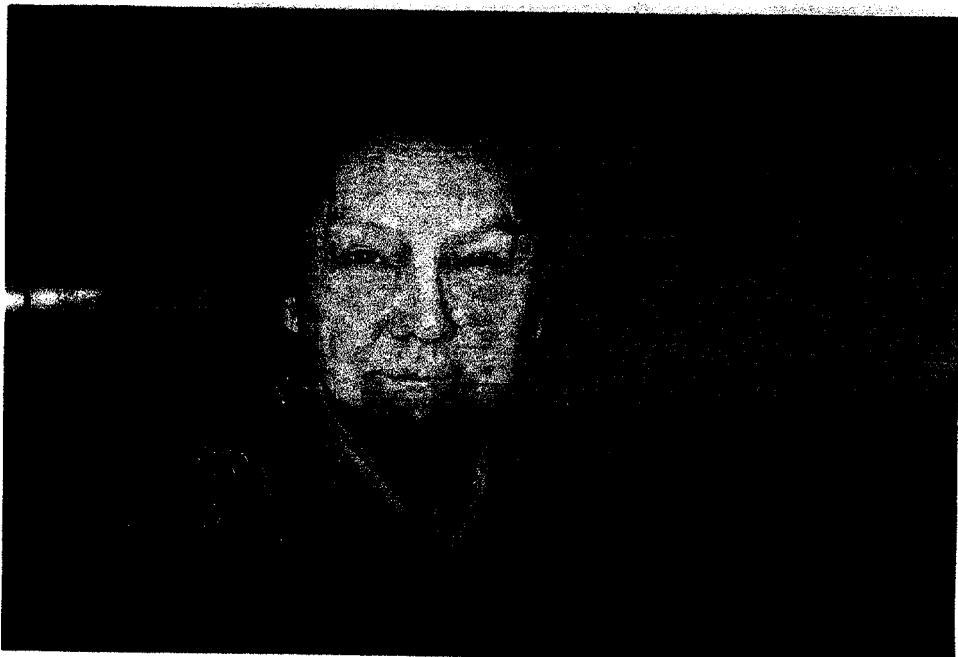
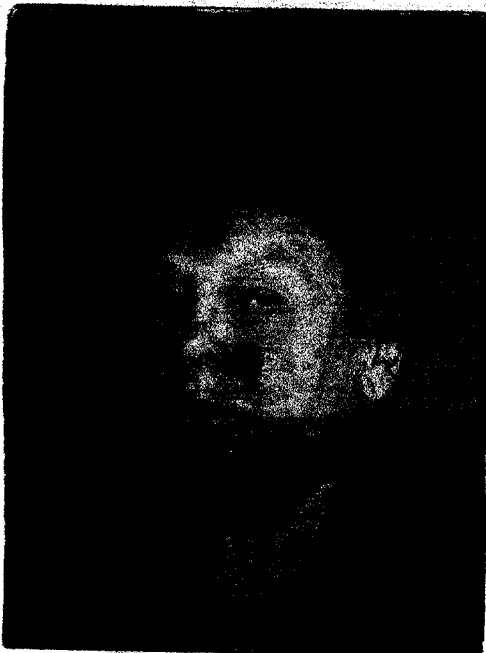
A FEW OF THE FACES I HAVE HAD FROM MY ENEMIES!!!  
MANY OF THESE ENEMIES ARE LIFE THREATENING SO I CARRY A EPEPA PEN FOR EMERGENCIES...  
FOR MY FACE BREAKOUTS I TAKE BETAMETHASONE VALET...AND PUT IT ON AS SOON AS THE RASH STARTS



*My clear  
skin*



*For my throat - Allegra works for me -*



*again for clear skin which one? Not sure*

# Flagrant fragrance

■ Wearing cologne or perfume to work? You may say you're offending your colleagues.

By Carol Graham  
Herald Staff Writer

A fragrance-free work environment may be more than just personal preference. For some people, it's a health issue.

More than 4,000 chemicals are used in fragrances. Of these, 95 percent are petroleum-based. No agency regulates the fragrance industry, yet opponents say perfume chemicals are as damaging to health as tobacco smoke.

Studies have shown that continued exposure to scented products can cause exhaustion, weakness, hay fever symptoms, headaches, rashes, swollen lymph glands, muscle aches and spasms, nausea, stomach cramps, vomiting, loss of concentration and seizures.

Altru Hospital has a strict policy against employees wearing fragrance at work. *Grand Forks N. Dak.*

"The scents are offensive to patients and staff who may have sensitivities and allergies," said Sandy Kowalczyk, administrative assistant to the executive nurse.

She said there is no resistance from staff about the policy because "people understand pretty well." She said there were complaints about perfumes and Colognes from the patients before the no-fragrance policy for hospital staff.

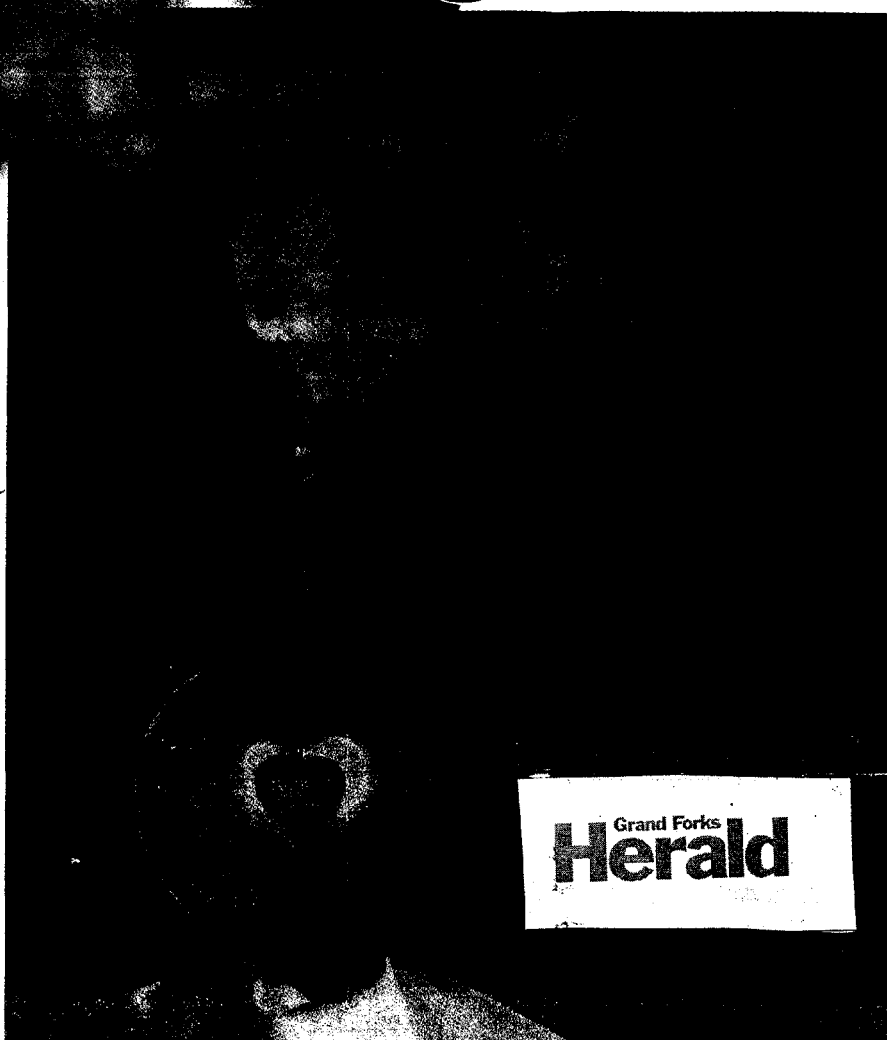
Don Shields, director of Grand Forks City and County Health Department, said the decision to make an office or workplace fragrance-free should be made on an individual basis. While the health department is smoke-free, he said there is no specific policy about wearing fragrance "but I would certainly not oppose it."

Grand Forks orthodontist John Nord displays a sign in his office that reads: "We ask that you keep perfumes, cologne and lotions to a minimum. Our patients and employees suffer from asthma and allergies." A receptionist said patients heed the sign, and there is little comment from the public.

Health Department nutritionist Bev Benda-Moe is adamant in her campaign against people wearing fragrance in public places. "Perfume is not made from flowers but from chemicals," said Benda-Moe, who works for the health department.

She said some people get ill from continued exposure.

"When we are out in public, we don't know who is sensitive. As a courtesy," she said, "we ask that people just not wear it at all. Some people generally wear fragrances when they get dressed up for church, a concert or theater performance. We suggest that they can get dressed up without perfumes." A change in thinking among health professionals is that fragrance is one of those things that is no longer socially acceptable. "The suggestion is that because people are sensitive or allergic, perfume and fragrances be reserved for the most intimate tete-a-tete."



Grand Forks  
**Herald**

J. Kyle Keener, Detroit Free Press

## The top 10 chemicals found in fragrance products

1. **Acetone.** Found in cologne, dishwashing liquid and detergent, nail polish remover.

Inhalation can cause dryness of the mouth and throat; dizziness, nausea, incoordination, slurred speech, drowsiness and, in severe exposures, coma.

2. **Benzaldehyde.** Found in perfume, cologne, hairspray, laundry bleach, deodorants, detergent, shaving cream, shampoo, bar soap, dishwasher detergent.

Local anesthetic, central nervous system depressant; causes irritation to the mouth, throat, eyes, skin, lungs and GI tract, causing nausea and abdominal pain. May cause kidney damage.

3. **Benzyl acetate.** Found in perfume, cologne, shampoo, fabric softener, stickup air freshener, dishwashing liquid and detergent, soap, hairspray, bleach, after shave, deodorants.

Carcinogenic (linked to pancreatic cancer); vapors irritating to eyes and respiratory passages.

4. **Benzyl alcohol.** Found in perfume, cologne, soap, shampoo, nail polish remover, air freshener, laundry bleach and detergent, lotion, deodorants, fabric softener.

Imitates upper respiratory tract. Can cause headache, nausea, vomiting, dizziness, drop in blood pressure.

5. **Camphor.** Found in perfume, shaving cream, nail enamel, fabric softener, dishwasher detergent, stickup air freshener.

Can cause irritation of eyes, nose and throat, dizziness, confusion, nausea, twitching muscles and convulsions.

6. **Ethanol.** Found in perfume, hairspray, shampoo, fabric softener, dishwashing liquid and detergent, laundry detergent, shaving cream, soap, lotion, air fresheners, nail

color and remover, paint and varnish remover.

Can cause fatigue, eye and respiratory irritation.

7. **Ethyl acetate.** Found in after shave, cologne, perfume, shampoo, nail color, nail enamel remover, fabric softener, dishwashing liquid.

Narcotic. Irritating to the eyes and respiratory tract; may cause headache and stupor. Can have a defatting effect on skin and may cause drying and cracking. May cause anemia with leukocytosis and damage to liver and kidneys.

8. **Limonene.** Found in perfume, cologne, disinfectant spray, bar soap, shaving cream, deodorants, nail color and remover, fabric softener, dishwashing liquid, air fresheners, after shave, bleach, paint and varnish remover. Carcinogenic.

9. **Linalool.** Found in perfume, cologne, bar soap, shampoo, hand lotion, nail enamel remover, hairspray, laundry detergent, dishwashing liquid, air fresheners, bleach powder, fabric softener, shaving cream, after shave, solid deodorant.

Narcotic.

10. **Methylene chloride.** Found in shampoo, cologne, paint and varnish remover.

Banned by the FDA in 1988. No enforcement possible due to trade secret laws protecting chemical fragrance industry. Carcinogenic. Absorbed, stored in body fat, it metabolizes to carbon monoxide, reducing oxygen-carrying capacity of the blood. Can cause headache, giddiness, stupor, irritability, fatigue, tingling in the limbs.

Source: Lance Wallace, Environmental Protection Agency.



**Holmes**

1300 Centennial Drive  
Chief River Falls, Minnesota 56701



DOCKETS MANAGEMENT BRANCH  
THE FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES, RM 1-23  
12420 PARKLAWN DRIVE.  
ROCKVILLE, MD 21857

ATTN: 99P-1340/CP 1

